

## **Title 22, California Code of Regulations**

### **ARTICLE 8. No Observable Effect Levels**

#### **§ 12801. General.**

(a) The determination of whether a level of exposure to a chemical known to the state to cause reproductive toxicity has no observable effect for purposes of Section 25249.10(c) of the Act shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of a chemical as known to the state to cause reproductive toxicity. Nothing in this article shall preclude a person from using evidence, standards, assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure has no observable effect at one thousand (1,000) times the level in question.

(b) A level of exposure to a listed chemical shall be deemed to have no observable effect, assuming exposure at one thousand times that level, provided that the level is determined:

(1) By means of an assessment that meets the standards described in Section 12803 to determine the maximum dose level having no observable effect, and dividing that level by one thousand (1,000) to arrive at the maximum allowable dose level, or

(2) By application of a specific regulatory level for the chemical in question as provided in Section 12805.

(c) For purposes of this article, “NOEL” shall mean that no observable effect level, which is the maximum dose level at which a chemical has no observable reproductive effect.

(d) The chemicals specifically contained in this article do not include all chemicals listed as causing reproductive toxicity for which there is a level of exposure which has no observable effect assuming exposure at one thousand times the level in question. The fact that a chemical does not specifically appear in this article does not mean that it has an observable effect at any level.

(e) This article establishes exposure levels solely for purposes of Section 25249.10(c) of the Act. Nothing in this article shall be construed to establish exposure levels for other regulatory purposes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

### **§ 12803. Assessment.**

(a) A quantitative assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which will have no observable effect, assuming the exposure at one thousand times the level in question. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause reproductive toxicity. In the absence of principles or assumptions scientifically more appropriate based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Only studies producing the reproductive effect which provides the basis for the determination that a chemical is known to the state to cause reproductive toxicity shall be utilized for the determination of the NOEL. Where multiple reproductive effects provide the basis for the determination that a chemical is known to the state to cause reproductive toxicity, the reproductive effect for which studies produce the lowest NOEL shall be utilized for the determination of the NOEL. The NOEL shall be the highest dose level which results in no observable reproductive effect expressed in milligrams of chemical per kilogram of bodyweight per day.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of an assessment considering such factors as the selection of the exposed and reference groups, the reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Animal bioassay studies for assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, and the route of exposure and the extent of occurrence of effects.

(4) The NOEL shall be based on the most sensitive study deemed to be of sufficient quality.

(5) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(6) When available data are of such quality that anatomic, physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the assessment.

(7) When data do not allow the determination of a NOEL, the lowest observable effect level (LOEL) shall be divided by 10 to establish a NOEL for purposes of assessment.

(b) The NOEL shall be converted to a milligram per day dose level by multiplying the assumed human body weight by the NOEL. When the applicable reproductive effect is upon the male, human body weight of 70 kilograms shall be assumed. When the applicable reproductive effect is upon the female or conceptus, human body weight of 58 kilograms shall be assumed.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

**§ 12805. Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity.**

(a) Exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical has no observable effect assuming exposure at one thousand (1,000) times that level.

(b) Chemical Name	Level (micrograms/day)
Benzene	24 (oral) 49 (inhalation)
Cadmium	4.1
Ethylene oxide	20.0
Lead	0.5
Linuron	460
Quizalofop ethyl	590
Toluene	7000

(c) Unless a specific level is otherwise provided in this section, an assessment by an agency of the state or federal government that is the substantial equivalent of the assessment described in subsection (a) of Section 12803, and establishes a maximum allowable dose level in the manner provided in paragraph (b)(1) of Section 12801, shall constitute the allowable dose level having no observable effect within the meaning of Section 25249.10(c) of the Act.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

**§ 12821. Level of Exposure to Chemicals Causing Reproductive Toxicity.**

(a) For purposes of the Act, “level in question” means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible, and does not include exposure to a listed chemical from any other source or product.

(b) For purposes of Section 25249.10(c) of the Act, the level of exposure to a chemical listed as causing reproductive toxicity shall be determined by multiplying the

level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to a given medium. The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity. (For example, an exposure of short duration is appropriate for a teratogenic chemical, whereas a chronic or protracted exposure is appropriate for one that retards fetal growth.)

(c) The following assumptions shall be used to calculate the reasonably anticipated rate of exposure to a chemical listed as causing reproductive toxicity, unless more specific and scientifically appropriate data are available:

(1) The assumptions set forth in subsection (d) of Section 12721 shall be used to calculate the reasonably anticipated rate of exposure to a chemical listed as causing reproductive toxicity, unless more specific and scientifically appropriate data are available.

(2) For exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. The rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.

(3) Where a maternal exposure to a chemical listed as causing reproductive toxicity has an effect on the conceptus (embryo or fetus), the level of exposure shall be based on the reasonably anticipated rate of exposure for the mother during the nine-month gestation period.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.